

OCT 8 - 2004

SECTION 9**510(k) SUMMARY**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

I. GENERAL INFORMATION**1. Device Name and Classification**

Product Name: **syngo Colonography - Software Package with Extended Functionality**

Classification Name: Accessory to Computed Tomography X-ray System

Classification Panel: Radiology

CFR Section: 21 CFR §892.2050

Device Class: Class II

Product Code: LLZ

2. Importer/Distributor Establishment:

Registration Number: 2240869

Siemens Medical Solutions, Inc.
51 Valley Stream Pkwy
Malvern, PA 19355

3. Manufacturing Facility:

Siemens AG, Medical Solutions
Henkestrasse 127
D-91052 Erlangen, Germany

4. Contact Person:

Mr. Rüdiger Körner
Manager Regulatory Submissions
Siemensstr.1; D-91301 Forchheim
Phone: +49 9191 18-9355
Fax: +49 9191 18-9988

5. Date of Preparation of Summary: August 24, 2004

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

1. General Safety and Effectiveness Concerns

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

2. Substantial Equivalence

The *syngo Colonography - Software Package with Extended Functionality*, addressed in this pre-market notification, is substantially equivalent to the following commercially available software package:

<u>Manufacturer</u>	<u>Product</u>	<u>510(k)</u>	<u>Clearance date</u>
1. Siemens	<i>syngo Colonography</i>		
	Software Package	K030982	April 08, 2003

In summary, Siemens is of the opinion that *syngo Colonography* Software Package with Extended Functionality does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate software components and the predicate device.

3. Device Description and Intended Use

This pre-market notification covers Siemens *syngo Colonography - Software Package with Extended Functionality*. It is based on Siemens *syngo* software platform.

syngo Colonography is a self-contained image analysis software package for evaluating CT volume data sets. This software package can also be utilized for evaluating suitable MR volume datasets. Combining enhanced commercially available digital image processing tools with an optimized workflow and reporting tools, the software is designed to support the physician in confirming the presence or absence of physician identified colon lesions (e.g. polyps) in addition to evaluation, documentation, and follow-up of any such lesions using standard or low-dose spiral CT or MR scanning.

The *syngo colonography* Software Package with Extended Functionality contains modifications for CT data only which support the user with a special workflow based

Enhanced Viewing). Furthermore workflow improvements, like “segmentation in global view”, “automatic size measurement”, “synchronization of prone and supine” and “unseen areas” are included in this software package.

This visualization tool allows for volumetric analysis of colonic lesion size over time, helping the physician to assess the changes in its growth. It is also designed to help the physician to classify conspicuous regions of tissue unambiguously having determined their size, dimensions, shape, and position.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 8 - 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Siemens AG Medical Solutions
% Mr. Stefan Preiss
Responsible Third Party Official
TÜV America, Inc.
TÜV Product Service
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K042605
Trade/Device Name: *syngo Colonography*-Software
Package with Extended Functionality
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and
communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: September 21, 2004
Received: September 24, 2004

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 3

INDICATION FOR USE

510(k) Number (if known): K042605

Device Name: ***syngo Colonography*** - Software Package with
Extended Functionality

Indications for Use:

syngo Colonography - Software Package with Extended Functionality is a self-contained image analysis software package for evaluating CT volume data sets. This software package can also be utilized for evaluating suitable MR volume datasets. Combining enhanced commercially available digital image processing tools with an optimized workflow and reporting tools, the software is designed to support the physician in confirming the presence or absence of physician identified colon lesions (e.g. polyps) in addition to evaluation, documentation, and follow-up of any such lesions using standard or low-dose spiral CT or MR scanning.

The *syngo Colonography* - Software Package with Extended Functionality contains modifications for CT data only which support the user with a special workflow based on automated segmentation for the visual identification of possible lesions (Polyp Enhanced Viewing). Furthermore workflow improvements, like "segmentation in global view", "automatic size measurement", "synchronization of prone and supine" and "unseen areas" are included in this software package.

This visualization tool allows for volumetric analysis of colonic lesion size over time, helping the physician to assess the changes in its growth. It is also designed to help the physician to classify conspicuous regions of tissue unambiguously having determined their size, dimensions, shape, and position.

The *syngo Colonography* - Software Package with Extended Functionality is limited to CT volume data sets.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRE, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number

K042605